

## § 310.545

initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action. After December 1, 1993, any such OTC drug product containing lobeline (in the form of lobeline sulfate or natural lobelia alkaloids or *Lobelia inflata* herb), povidone-silver nitrate, silver acetate, or any other ingredients initially introduced or initially delivered for introduction into interstate commerce that is not in compliance with this section is subject to regulatory action.

[58 FR 31241, June 1, 1993]

### § 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) A number of active ingredients have been present in OTC drug products for various uses, as described below. However, based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses:

#### (1) Topical acne drug products.

Alcloxa  
Alkyl isoquinolinium bromide  
Aluminum chlorohydrate  
Aluminum hydroxide  
Benzocaine  
Benzoic acid  
Boric acid  
Calcium polysulfide  
Calcium thiosulfate  
Camphor  
Chloroxylenol  
Cloxyquin  
Coal tar  
Dibenzothiophene  
Estrone  
Magnesium aluminum silicate  
Magnesium sulfate  
Phenol  
Phenolate sodium  
Phenyl salicylate  
Povidone-iodine  
Pyrilamine maleate  
Resorcinol (as single ingredient)  
Resorcinol monoacetate (as single ingredient)  
Salicylic acid (over 2 up to 5 percent)  
Sodium borate  
Sodium thiosulfate  
Tetracaine hydrochloride  
Thymol  
Vitamin E  
Zinc oxide  
Zinc stearate

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Zinc sulfide

(2) *Anticaries drug products*—(i) *Approved as of May 7, 1991.*

Hydrogen fluoride  
Sodium carbonate  
Sodium monofluorophosphate (6 percent rinse)  
Sodium phosphate

(ii) *Approved as of October 7, 1996.*

Calcium sucrose phosphate  
Dicalcium phosphate dihydrate  
Disodium hydrogen phosphate<sup>1</sup>  
Phosphoric acid<sup>1</sup>  
Sodium dihydrogen phosphate  
Sodium dihydrogen phosphate monohydrate  
Sodium phosphate, dibasic anhydrous reagent<sup>1</sup>

(3) *Antidiarrheal drug products.*

Aluminum hydroxide  
Atropine sulfate  
Calcium carbonate  
Carboxymethylcellulose sodium  
Glycine  
Homatropine methylbromide  
Hyoscyamine sulfate  
Lactobacillus acidophilus  
Lactobacillus bulgaricus  
Opium, powdered  
Opium tincture  
Paregoric  
Phenyl salicylate  
Scopolamine hydrobromide  
Zinc phenolsulfonate

(4) *Antiperspirant drug products.*

Alum, potassium  
Aluminum bromohydrate  
Aluminum chloride (alcoholic solutions)  
Aluminum chloride (aqueous solution) (aerosol only)  
Aluminum sulfate  
Aluminum sulfate, buffered (aerosol only)  
Sodium aluminum chlorohydroxy lactate

(5) [Reserved]

(6) *Cold, cough, allergy, bronchodilator, and antiasthmatic drug products*—(i) *Antihistamine drug products*—(A) *Ingredients.*

Methapyrilene hydrochloride  
Methapyrilene fumarate  
Thenylidamine hydrochloride

(B) *Ingredients.*

Phenyltoloxamine dihydrogen citrate  
Methapyrilene hydrochloride

<sup>1</sup>These ingredients are nonmonograph except when used to prepare acidulated phosphate fluoride treatment rinses identified in § 355.10(a)(3) of this chapter.

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Methapyrilene fumarate  
Thenyldiamine hydrochloride

(ii) *Nasal decongestant drug products—*  
(A) *Approved as of May 7, 1991.*

Allyl isothiocyanate  
Camphor (lozenge)  
Creosote, beechwood (oral)  
Eucalyptol (lozenge)  
Eucalyptol (mouthwash)  
Eucalyptus oil (lozenge)  
Eucalyptus oil (mouthwash)  
Menthol (mouthwash)  
Peppermint oil (mouthwash)  
Thenyldiamine hydrochloride  
Thymol  
Thymol (lozenge)  
Thymol (mouthwash)  
Turpentine oil

(B) *Approved as of August 23, 1995.*

Bornyl acetate (topical)  
Cedar leaf oil (topical)  
Creosote, beechwood (topical)  
Ephedrine (oral)  
Ephedrine hydrochloride (oral)  
Ephedrine sulfate (oral)  
Racephedrine hydrochloride (oral/topical)

(iii) *Expectorant drug products.*

Ammonium chloride  
Antimony potassium tartrate  
Beechwood creosote  
Benzoin preparations (compound tincture of benzoin, tincture of benzoin)  
Camphor  
Chloroform  
Eucalyptol/eucalyptus oil  
Horehound  
Iodides (calcium iodide anhydrous, hydroidic acid syrup, iodized lime, potassium iodide)  
Ipecac  
Ipecac fluidextract  
Ipecac syrup  
Menthol/peppermint oil  
Pine tar preparations (extract white pine compound, pine tar, syrup of pine tar, compound white pine syrup, white pine)  
Potassium guaiacolsulfonate  
Sodium citrate  
Squill preparations (squill, squill extract)  
Terpin hydrate preparations (terpin hydrate, terpin hydrate elixir)  
Tolu preparations (tolu, tolu balsam, tolu balsam tincture)  
Turpentine oil (spirits of turpentine)

(iv) *Bronchodilator drug products—*(A)  
*Approved as of October 2, 1987.*

Aminophylline  
Belladonna alkaloids  
Euphorbia pilulifera  
Metaproterenol sulfate  
Methoxyphenamine hydrochloride  
Pseudoephedrine hydrochloride

Pseudoephedrine sulfate  
Theophylline, anhydrous  
Theophylline calcium salicylate  
Theophylline sodium glycinate

(B) *Approved as of January 29, 1996.*  
Any combination drug product containing theophylline (e.g., theophylline and ephedrine, or theophylline and ephedrine and phenobarbital).

(C) *Approved as of June 19, 1996.* Any ingredient(s) in a pressurized metered-dose inhaler container.

(D) *Approved as of October 29, 2001.* Any oral bronchodilator active ingredient (e.g., ephedrine, ephedrine hydrochloride, ephedrine sulfate, racephedrine hydrochloride, or any other ephedrine salt) in combination with any analgesic(s) or analgesic-antipyretic(s), anticholinergic, antihistamine, oral antitussive, or stimulant active ingredient.

(7) *Dandruff/seborrheic dermatitis/psoriasis drug products.*

Alkyl isoquinolinium bromide  
Allantoin  
Benzalkonium chloride  
Benzethonium chloride  
Boric acid  
Calcium undecylenate  
Captan  
Chloroxylenol  
Colloidal oatmeal  
Cresol, saponated  
Ethohexadiol  
Eucalyptol  
Juniper tar  
Lauryl isoquinolinium bromide  
Menthol  
Mercury oleate  
Methylbenzethonium chloride  
Methyl salicylate  
Phenol  
Phenolate sodium  
Pine tar  
Povidone-iodine  
Resorcinol  
Sodium borate  
Sodium salicylate  
Thymol  
Undecylenic acid

(8) *Digestive aid drug products—*(i) *Approved as of May 7, 1991.*

Bismuth sodium tartrate  
Calcium carbonate  
Cellulase  
Dehydrocholic acid  
Dihydroxyaluminum sodium carbonate  
Duodenal substance  
Garlic, dehydrated  
Glutamic acid hydrochloride  
Hemicellulase

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Homatropine methylbromide  
Magnesium hydroxide  
Magnesium trisilicate  
Ox bile extract  
Pancreatin  
Pancrelipase  
Papain  
Peppermint oil  
Pepsin  
Sodium bicarbonate  
Sodium citrate  
Sorbitol

(ii) *Approved as of November 10, 1993.*

Alcohol  
Aluminum hydroxide  
Amylase  
Anise seed  
Aromatic powder  
Asafetida  
Aspergillus oryza enzymes (except lactase enzyme derived from *Aspergillus oryzae*)  
Bacillus acidophilus  
Bean  
Belladonna alkaloids  
Belladonna leaves, powdered extract  
Betaine hydrochloride  
Bismuth subcarbonate  
Bismuth subgallate  
Black radish powder  
Blessed thistle (*cnicus benedictus*)  
Buckthorn  
Calcium gluconate  
Capsicum  
Capsicum, fluid extract of  
Carbon  
Cascara sagrada extract  
Catechu, tincture  
Catnip  
Chamomile flowers  
Charcoal, wood  
Chloroform  
Cinnamon oil  
Cinnamon tincture  
Citrus pectin  
Diastase  
Diastase malt  
Dog grass  
Elecampane  
Ether  
Fennel acid  
Galega  
Ginger  
Glycine  
Hydrastis canadensis (golden seal)  
Hectorite  
Horsetail  
Huckleberry  
Hydrastis fluid extract  
Hydrochloric acid  
Iodine  
Iron ox bile  
Johnswort  
Juniper  
Kaolin, colloidal  
Knotgrass  
Lactic acid

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Lactose  
Lavender compound, tincture of  
Linden  
Lipase  
Lysine hydrochloride  
Mannitol  
Mycozyme  
Myrrh, fluid extract of  
Nettle  
Nickel-pectin  
Nux vomica extract  
Orthophosphoric acid  
Papaya, natural  
Pectin  
Peppermint  
Peppermint spirit  
Phenacetin  
Potassium bicarbonate  
Potassium carbonate  
Protease  
Prolase  
Rhubarb fluid extract  
Senna  
Sodium chloride  
Sodium salicylate  
Stem bromelain  
Strawberry  
Strychnine  
Tannic acid  
Trillium  
Woodruff

(iii) Charcoal, activated

(9) [Reserved]

(10) *External analgesic drug products—*

(i) *Analgesic and anesthetic drug products.*

Aspirin  
Chloral hydrate  
Chlorobutanol  
Cyclomethycaine sulfate  
Eugenol  
Hexylresorcinol  
Methapyrilene hydrochloride  
Salicylamide  
Thymol

(ii) *Counterirritant drug products.*

Chloral hydrate  
Eucalyptus oil

(iii) *Male genital desensitizer drug products.*

Benzyl alcohol  
Camphorated metacresol  
Ephedrine hydrochloride

(iv) *Diaper rash drug products.*

Any ingredient(s) labeled with claims or directions for use in the treatment and/or prevention of diaper rash.

(v) *Fever blister and cold sore treatment drug products.*

Allyl isothiocyanate  
Aspirin

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Bismuth sodium tartrate  
Camphor (exceeding 3 percent)  
Capsaicin  
Capsicum  
Capsicum oleoresin  
Chloral hydrate  
Chlorobutanol  
Cyclomethycaine sulfate  
Eucalyptus oil  
Eugenol  
Glycol salicylate  
Hexylresorcinol  
Histamine dihydrochloride  
Menthol (exceeding 1 percent)  
Methapyrilene hydrochloride  
Methyl nicotinate  
Methyl salicylate  
Pectin  
Salicylamide  
Strong ammonia solution  
Tannic acid  
Thymol  
Tripeleminamine hydrochloride  
Trolamine salicylate  
Turpentine oil  
Zinc sulfate

(vi) *Insect bite and sting drug products.*

Alcohol  
Alcohol, ethoxylated alkyl  
Benzalkonium chloride  
Calamine  
Ergot fluidextract  
Ferric chloride  
Panthenol  
Peppermint oil  
Pyrimilamine maleate  
Sodium borate  
Trolamine salicylate  
Turpentine oil  
Zinc oxide  
Zirconium oxide

(vii) *Poison ivy, poison oak, and poison sumac drug products.*

Alcohol  
Aspirin  
Benzethonium chloride  
Benzocaine (0.5 to 1.25 percent)  
Bithionol  
Calamine  
Cetalkonium chloride  
Chloral hydrate  
Chlorobutanol  
Chlorpheniramine maleate  
Creosote, beechwood  
Cyclomethycaine sulfate  
Dexpantenol  
Diperodon hydrochloride  
Eucalyptus oil  
Eugenol  
Glycerin  
Glycol salicylate  
Hectorite  
Hexylresorcinol  
Hydrogen peroxide

Impatiens biflora tincture  
Iron oxide  
Isopropyl alcohol  
Lanolin  
Lead acetate  
Merbromin  
Mercuric chloride  
Methapyrilene hydrochloride  
Panthenol  
Parethoxycaine hydrochloride  
Phenyltoloxamine dihydrogen citrate  
Povidone-vinylacetate copolymers  
Pyrimilamine maleate  
Salicylamide  
Salicylic acid  
Simethicone  
Sulfur  
Tannic acid  
Thymol  
Trolamine salicylate  
Turpentine oil  
Zirconium oxide  
Zyloxin

(11) [Reserved]

(12) *Laxative drug products—(i) Bulk laxatives.*

Agar  
Carrageenan (degraded)  
Carrageenan (native)  
Guar gum

(ii) *Saline laxative.*

Tartaric acid

(iii) *Stool softener.*

Poloxamer 188

(iv)(A) *Stimulant laxatives—Approved as of May 7, 1991.*

Aloin  
Bile salts/acids  
Calcium pantothenate  
Calomel  
Colocynth  
Elaterin resin  
Frangula  
Gamboge  
Ipomea  
Jalap  
Ox bile  
Podophyllum resin  
Prune concentrate dehydrate  
Prune powder  
Rhubarb, Chinese  
Sodium Oleate

(iv)(B) *Stimulant laxatives—Approved as of January 29, 1999.*

Danthron  
Phenolphthalein

(C) *Stimulant laxatives—Approved as of November 5, 2002.*

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Aloe ingredients (aloe, aloe extract, aloe flower extract)  
 Cascara sagrada ingredients (casanthranol, cascara fluidextract aromatic, cascara sagrada bark, cascara sagrada extract, cascara sagrada fluidextract).

(13) [Reserved]

(14) *Oral health care drug products (nonantimicrobial).*

Antipyrine  
 Camphor  
 Cresol  
 Dibucaine  
 Dibucaine hydrochloride  
 Eucalyptol  
 Lidocaine  
 Lidocaine hydrochloride  
 Methyl salicylate  
 Myrrh tincture  
 Pyrilamine maleate  
 Sorbitol  
 Sugars  
 Tetracaine  
 Tetracaine hydrochloride  
 Thymol

(a) \* \* \*

(15) *Topical otic drug products—(i) For the prevention of swimmer's ear and for the drying of water-clogged ears, approved as of May 7, 1991.*

Acetic acid

(ii) *For the prevention of swimmer's ear, approved as of August 15, 1995.*

Glycerin and anhydrous glycerin  
 Isopropyl alcohol

(16) *Poison treatment drug products.*

Ipecac fluidextract  
 Ipecac tincture  
 Zinc sulfate

(17) *Skin bleaching drug products.*

Mercury, ammoniated

(18) *Skin protectant drug products. (i) Ingredients.*

Allantoin (wound healing claims only)  
 Sulfur  
 Tannic acid  
 Zinc acetate (wound healing claims only)

(ii) *Astringent drug products.*

Acetone  
 Alcohol  
 Alum, ammonium  
 Alum, potassium  
 Aluminum chlorhydroxy complex  
 Aromatics  
 Benzalkonium chloride  
 Benzethonium chloride  
 Benzocaine

Benzoic acid  
 Boric acid  
 Calcium acetate  
 Camphor gum  
 Clove oil  
 Colloidal oatmeal  
 Cresol  
 Cupric sulfate  
 Eucalyptus oil  
 Eugenol  
 Ferric subsulfate (Monsel's Solution)  
 Honey  
 Isopropyl alcohol  
 Menthol  
 Methyl salicylate  
 Oxyquinoline sulfate  
 P-t-butyl-m-cresol  
 Peppermint oil  
 Phenol  
 Polyoxeethylene laurate  
 Potassium ferrocyanide  
 Sage oil  
 Silver nitrate  
 Sodium borate  
 Sodium diacetate  
 Talc  
 Tannic acid glycerite  
 Thymol  
 Topical starch  
 Zinc chloride  
 Zinc oxide  
 Zinc phenolsulfonate  
 Zinc stearate  
 Zinc sulfate

(iii) *Diaper rash drug products.*

Aluminum hydroxide  
 Cocoa butter  
 Cysteine hydrochloride  
 Glycerin  
 Protein hydrolysate  
 Racemethionine  
 Sulfur  
 Tannic acid  
 Zinc acetate  
 Zinc carbonate

(iv) *Fever blister and cold sore treatment drug products.*

Bismuth subnitrate  
 Boric acid  
 Pyridoxine hydrochloride  
 Sulfur  
 Tannic acid  
 Topical starch  
 Trolamine  
 Zinc sulfate

(v) *Insect bite and sting drug products.*

Alcohol  
 Alcohol, ethoxylated alkyl  
 Ammonia solution, strong  
 Ammonium hydroxide  
 Benzalkonium chloride  
 Camphor  
 Ergot fluidextract

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Ferric chloride  
Menthol  
Peppermint oil  
Phenol  
Pyrilamine maleate  
Sodium borate  
Trolamine  
Turpentine oil  
Zirconium oxide

(vi) *Poison ivy, poison oak, and poison sumac drug products.*

Alcohol  
Anion and cation exchange resins buffered  
Benzethonium chloride  
Benzocaine  
Benzyl alcohol  
Bismuth subnitrate  
Bithionol  
Boric acid  
Camphor  
Cetalkonium chloride  
Chloral hydrate  
Chlorpheniramine maleate  
Creosote  
Diperodon hydrochloride  
Diphenhydramine hydrochloride  
Eucalyptus oil  
Ferric chloride  
Glycerin  
Hectorite  
Hydrogen peroxide  
Impatiens biflora tincture  
Iron oxide  
Isopropyl alcohol  
Lanolin  
Lead acetate  
Lidocaine  
Menthol  
Merbromin  
Mercuric chloride  
Panthenol  
Parethoxycaïne hydrochloride  
Phenol  
Phenyltoloxamine dihydrogen citrate  
Povidone-vinylacetate copolymers  
Salicylic acid  
Simethicone  
Tannic acid  
Topical starch  
Trolamine  
Turpentine oil  
Zirconium oxide  
Zyloxin

(19) [Reserved]

(20) *Weight control drug products.*

Alcohol  
Alfalfa  
Alginic acid  
Anise oil  
Arginine  
Ascorbic acid  
Bearberry  
Biotin  
Bone marrow, red

Buchu  
Buchu, potassium extract  
Caffeine  
Caffeine citrate  
Calcium  
Calcium carbonate  
Calcium caseinate  
Calcium lactate  
Calcium pantothenate  
Carboxymethylcellulose sodium  
Carrageenan  
Cholecalciferol  
Choline  
Chondrus  
Citric acid  
Cnicus benedictus  
Copper  
Copper gluconate  
Corn oil  
Corn syrup  
Corn silk, potassium extract  
Cupric sulfate  
Cyanocobalamin (vitamin B<sub>12</sub>)  
Cystine  
Dextrose  
Docusate sodium  
Ergocalciferol  
Ferric ammonium citrate  
Ferric pyrophosphate  
Ferrous fumarate  
Ferrous gluconate  
Ferrous sulfate (iron)  
Flax seed  
Folic acid  
Fructose  
Guar gum  
Histidine  
Hydrastis canadensis  
Inositol  
Iodine  
Isoleucine  
Juniper, potassium extract  
Karaya gum  
Kelp  
Lactose  
Lecithin  
Leucine  
Liver concentrate  
Lysine  
Lysine hydrochloride  
Magnesium  
Magnesium oxide  
Malt  
Maltodextrin  
Manganese citrate  
Mannitol  
Methionine  
Methylcellulose  
Mono- and di-glycerides  
Niacinamide  
Organic vegetables  
Pancreatin  
Pantothenic acid  
Papain  
Papaya enzymes  
Pepsin  
Phenacetin

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Phenylalanine  
Phosphorus  
Phytolacca  
Pineapple enzymes  
Plantago seed  
Potassium citrate  
Pyridoxine hydrochloride (vitamin B<sub>6</sub>)  
Riboflavin  
Rice polishings  
Saccharin  
Sea minerals  
Sesame seed  
Sodium  
Sodium bicarbonate  
Sodium caseinate  
Sodium chloride (salt)  
Soybean protein  
Soy meal  
Sucrose  
Thiamine hydrochloride (vitamin B<sub>1</sub>)  
Thiamine mononitrate (vitamin B<sub>1</sub> mono-  
nitrate)  
Threonine  
Tricalcium phosphate  
Tryptophan  
Tyrosine  
Uva ursi, potassium extract  
Valine  
Vegetable  
Vitamin A  
Vitamin A acetate  
Vitamin A palmitate  
Vitamin E  
Wheat germ  
Xanthan gum  
Yeast

(21) *Ophthalmic drug products.*

(i) *Ophthalmic anesthetic drug products.*

Antipyrine  
Piperocaine hydrochloride

(ii) *Ophthalmic anti-infective drug products.*

Boric acid  
Mild silver protein  
Yellow mercuric oxide

(iii) *Ophthalmic astringent drug products.*

Infusion of rose petals

(iv) *Ophthalmic demulcent drug products.*

Polyethylene glycol 6000

(v) *Ophthalmic vasoconstrictor drug products.*

Phenylephrine hydrochloride (less than 0.08 percent)

(22) *Topical antifungal drug products.*

(i) *Diaper rash drug products.* Any ingredient(s) labeled with claims or di-

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rections for use in the treatment and/or prevention of diaper rash.

(ii) *Ingredients.*

Alcloxa  
Alum, potassium  
Aluminum sulfate  
Amyltriethersols, secondary  
Basic fuchsin  
Benzethonium chloride  
Benzoic acid  
Benzoxiquine  
Boric acid  
Camphor  
Candididin  
Chlorothymol  
Coal tar  
Dichlorophen  
Menthol  
Methylparaben  
Oxyquinoline  
Oxyquinoline sulfate  
Phenol  
Phenolate sodium  
Phenyl salicylate  
Propionic acid  
Propylparaben  
Resorcinol  
Salicylic acid  
Sodium borate  
Sodium caprylate  
Sodium propionate  
Sulfur  
Tannic acid  
Thymol  
Tolindate  
Triacetin  
Zinc caprylate  
Zinc propionate

(iii) Any ingredient(s) labeled with claims or directions for use on the scalp or on the nails.

(iv) *Ingredients.*

Camphorated metacresol  
Chloroxylenol  
*m*-cresol  
Nystatin

(23) *Internal analgesic drug products.*

(i) *Approved as of November 10, 1993.*

Aminobenzoic acid  
Antipyrine  
Aspirin, aluminum  
Calcium salicylate  
Codeine  
Codeine phosphate  
Codeine sulfate  
Iodoantipyrine  
Lysine aspirin  
Methapyrilene fumarate  
Phenacetin  
Pheniramine maleate  
Pyrimamine maleate  
Quinine  
Salsalate

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Sodium aminobenzoate

(ii) *Approved as of* February 22, 1999.

Any atropine ingredient

Any ephedrine ingredient

(24) *Orally administered menstrual drug products.* (i) *Approved as of* November 10, 1993.

Alcohol

Alfalfa leaves

Aloes

Asclepias tuberosa

Asparagus

Barosma

Bearberry (extract of uva ursi)

Bearberry fluidextract (extract of bearberry)

Blessed thistle (cnicus benedictus)

Buchu powdered extract (extract of buchu)

Calcium lactate

Calcium pantothenate

Capsicum oleoresin

Cascara fluidextract, aromatic (extract of cascara)

Chlorprophenpyridamine maleate

Cimicifuga racemosa

Codeine

Collinsonia (extract stone root)

Corn silk

Couch grass

Dog grass extract

Ethyl nitrite

Ferric chloride

Ferrous sulfate

Gentiana lutea (gentian)

Glycyrrhiza (licorice)

Homatropine methylbromide

Hydrangea, powdered extract (extract of hydrangea)

Hydrastis canadensis (golden seal)

Hyoscyamine sulfate

Juniper oil (oil of juniper)

Magnesium sulfate

Methapyrilene hydrochloride

Methenamine

Methylene blue

Natural estrogenic hormone

Niacinamide

Nutmeg oil (oil of nutmeg)

Oil of erigeron

Parsley

Peppermint spirit

Pepsin, essence

Phenacetin

Phenindamine tartrate

Phenyl salicylate

Piscidia erythrina

Pipsissewa

Potassium acetate

Potassium nitrate

Riboflavin

Saw palmetto

Senecio aureus

Sodium benzoate

Sodium nitrate

Sucrose

Sulferated oils of turpentine

Taraxacum officinale

Theobromine sodium salicylate

Theophylline

Thiamine hydrochloride

Triticum

Turpentine, venice (venice turpentine)

Urea

(ii) *Approved as of* February 22, 1999.

Any atropine ingredient

Any ephedrine ingredient

(25) *Pediculicide drug products*—(i) *Approved as of* November 10, 1993.

Benzocaine

Benzyl alcohol

Benzyl benzoate

Chlorophenothane (dichlorodiphenyl tri-chloroethane)

Coconut oil soap, aqueous

Copper oleate

Docusate sodium

Formic acid

Isobornyl thiocynoacetate

Picrotoxin

Propylene glycol

Sabadilla alkaloids

Sulfur, sublimed

Thiocynoacetate

(ii) *Approved as of* June 14, 1994. The combination of pyrethrum extract (formerly named pyrethrins) and piperonyl butoxide in an aerosol dosage formulation.

(26) *Anorectal drug products*—(i) *Anticholinergic drug products.*

Atropine

Belladonna extract

(ii) *Antiseptic drug products.*

Boric acid

Boroglycerin

Hydrastis

Phenol

Resorcinol

Sodium salicylic acid phenolate

(iii) *Astringent drug products.*

Tannic acid

(iv) *Counterirritant drug products.*

Camphor (greater than 3 to 11 percent)

Hydrastis

Menthol (1.25 to 16 percent)

Turpentine oil (rectified) (6 to 50 percent)

(v) *Keratolytic drug products.*

Precipitated sulfur

Sublimed sulfur

(vi) *Local anesthetic drug products.*

Diperodon



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Phenacaine hydrochloride

(vii) *Other drug products.*

Collinsonia extract  
Escherichia coli vaccines  
Lappa extract  
Leptandra extract  
Live yeast cell derivative  
Mullein

(viii) *Protectant drug products.*

Bismuth oxide  
Bismuth subcarbonate  
Bismuth subgallate  
Bismuth subnitrate  
Lanolin alcohols

(ix) *Vasoconstrictor drug products.*

Epinephrine undecylenate

(x) *Wound healing drug products.*

Cholecalciferol  
Cod liver oil  
Live yeast cell derivative  
Peruvian balsam  
Shark liver oil  
Vitamin A

(27) *Topical antimicrobial drug products—(i) First aid antiseptic drug products.*

Ammoniated mercury  
Calomel (mercurous chloride)  
Merbromin (mercurochrome)  
Mercufenol chloride (ortho-chloromercuriphenol, ortho-hydroxyphenylmercuric chloride)  
Mercuric chloride (bichloride of mercury, mercury chloride)  
Mercuric oxide, yellow  
Mercuric salicylate  
Mercuric sulfide, red  
Mercury  
Mercury oleate  
Mercury sulfide  
Nitromersol  
Para-chloromercuriphenol  
Phenylmercuric nitrate  
Thimerosal  
Vitromersol  
Zyloxin

(ii) *Diaper rash drug products.*

Para-chloromercuriphenol  
Any other ingredient containing mercury

(28) *Vaginal contraceptive drug products—(i) Approved as of October 22, 1998.*

Dodecaethylene glycol monolaurate (polyethylene glycol 600 monolaurate)  
Laureth 10S  
Methoxypolyoxyethyleneglycol 550 laurate  
Phenylmercuric acetate  
Phenylmercuric nitrate

Any other ingredient containing mercury

(ii) *Approved as of November 5, 2002.*

Octoxynol 9

(29) *Sunscreen drug products.*

Diethanolamine methoxycinnamate  
Digalloyl trioleate  
Ethyl 4-[bis(hydroxypropyl)] aminobenzoate  
Glyceryl aminobenzoate  
Lawsone with dihydroxyacetone  
Red petrolatum

(30) [Reserved]

(b) Any OTC drug product that is labeled, represented, or promoted for the uses specified and containing any active ingredient(s) as specified in paragraph (a) of this section is regarded as a new drug within the meaning of section 210(p) of the Federal Food, Drug, and Cosmetic Act (the Act), for which an approved new drug application under section 505 of the Act and part 314 of this chapter is required for marketing. In the absence of an approved new drug application, such product is also misbranded under section 502 of the Act.

(c) Clinical investigations designed to obtain evidence that any drug product labeled, represented, or promoted for the OTC uses and containing any active ingredient(s) as specified in paragraph (a) of this section is safe and effective for the purpose intended must comply with the requirements and procedures governing the use of investigational new drugs set forth in part 312 of this chapter.

(d) Any OTC drug product that is not in compliance with this section is subject to regulatory action if initially introduced or initially delivered for introduction into interstate commerce after the dates specified in paragraphs (d)(1) through (d)(29) of this section.

(1) May 7, 1991, for products subject to paragraphs (a)(1) through (a)(2)(i), (a)(3) through (a)(4), (a)(6)(i)(A), (a)(6)(ii)(A), (a)(7) (except as covered by paragraph (d)(3) of this section), (a)(8)(i), (a)(10)(i) through (a)(10)(iii), (a)(12)(i) through (a)(12)(iv)(A), (a)(14) through (a)(15)(i), and (a)(16) through (a)(18) of this section.

(2) February 10, 1992, for products subject to paragraph (a)(20) of this section.

(3) December 4, 1992, for products subject to paragraph (a)(7) of this section

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that contain menthol as an anti-pruritic in combination with the antidandruff ingredient coal tar identified in §358.710(a)(1) of this chapter.

(4) February 28, 1990, for products subject to paragraph (a)(6)(iii) of this section, except those that contain ipecac.

(5) September 14, 1993, for products subject to paragraph (a)(6)(iii) of this section that contain ipecac.

(6) December 9, 1993, for products subject to paragraph (a)(6)(i)(B) of this section.

(7) March 6, 1989, for products subject to paragraph (a)(21) of this section, except those that contain ophthalmic anti-infective ingredients listed in paragraph (a)(21)(ii).

(8) June 18, 1993, for products subject to paragraph (a)(21) of this section that contain ophthalmic anti-infective ingredients.

(9) June 18, 1993, for products subject to paragraph (a)(10)(iv) of this section.

(10) June 18, 1993, for products subject to paragraph (a)(22)(i) of this section.

(11) November 10, 1993, for products subject to paragraphs (a)(8)(ii), (a)(10)(v) through (a)(10)(vii), (a)(18)(ii) (except products that contain ferric subsulfate) through (a)(18)(vi), (a)(22)(ii), (a)(23)(i), (a)(24)(i), and (a)(25) of this section.

(12) March 2, 1994, for products subject to paragraph (a)(22)(iii) of this section.

(13) August 5, 1991, for products subject to paragraphs (a)(26) of this section, except for those that contain live yeast cell derivative.

(14) September 2, 1994, for products subject to paragraph (a)(26)(vii) and (a)(26)(x) of this section that contain live yeast cell derivative.

(15) September 23, 1994, for products subject to paragraph (a)(22)(iv) of this section.

(16) June 14, 1994, for products subject to paragraph (a)(25)(ii) of this section.

(17) [Reserved]

(18) August 15, 1995, for products subject to paragraph (a)(15)(ii) of this section.

(19) October 2, 1987, for products subject to paragraph (a)(6)(iv)(A) of this section.

(20) January 29, 1996, for products subject to paragraph (a)(6)(iv)(B) of this section.

(21) April 21, 1994, for products subject to paragraph (a)(8)(iii) of this section.

(22) April 21, 1993, for products subject to paragraph (a)(18)(ii) of this section that contain ferric subsulfate.

(23) August 23, 1995, for products subject to paragraph (a)(6)(ii)(B) of this section.

(24) October 7, 1996, for products subject to paragraph (a)(2)(ii) of this section.

(25) June 19, 1996, for products subject to paragraph (a)(6)(iv)(C) of this section.

(26) February 22, 1999, for products subject to paragraphs (a)(23)(ii) and (a)(24)(ii) of this section.

(27) [Reserved]

(28) October 22, 1998, for products subject to paragraphs (a)(27) and (a)(28)(i) of this section.

(29) January 29, 1999, for products subject to paragraph (a)(12)(iv)(B) of this section.

(30) November 5, 2002, for products subject to paragraph (a)(12)(iv)(C) of this section.

(31) December 31, 2002, for products subject to paragraph (a)(29) of this section.

(32) [Reserved]

(33) October 29, 2001, for products subject to paragraph (a)(6)(iv)(D) of this section.

(34)–(35)[Reserved]

(36) November 5, 2002, for products subject to paragraph (a)(28)(ii) of this section.

[55 FR 46919, Nov. 7, 1990]

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting §310.545, see the List of CFR Sections Affected, which appears in the Finding Aids section of the printed volume and on GPO Access.

EFFECTIVE DATE NOTE: At 61 FR 9571, Mar. 8, 1996, in §310.545 in paragraph (a)(6)(ii)(B), the entry for “l-desoxyephedrine (topical)” was stayed until further notice.